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NEW YORK, NY 10112

In re Application of	:
Birger Sorensen	:
Serial No.: 10/659,324	: PETITION DECISION
Filed: September 11, 2003	:
Attorney Docket No.: 02833.4001LO	:

This is in response to the petition under 37 CFR 1.144, filed October 5, 2006, requesting withdrawal of an improper restriction requirement. The delay in acting upon this decision is regretted.

BACKGROUND

A review of the file history shows that this application was filed on September 11, 2003, under 35 U.S.C. 111. The examiner mailed to applicants on June 3, 2005, a restriction requirement, wherein four distinct inventions (Groups I-IV) were identified and rationale set forth establishing the examiner's position. The claims were restricted as follows:

I. Claims 16-32, drawn to SEQ ID NO: 1, classified in class 424, subclass 208.1.

II. Claims 16-32, drawn to SEQ ID NO: 4, classified in class 424, subclass 208.1.

III. Claims 16-32, drawn to SEQ ID NO: 9, classified in class 424, subclass 208.1.

IV. Claims 16-32, drawn to SEQ ID NO: 15, classified in class 424, subclass 208.1.

An election of species within the elected invention was also required between each of the variants of the sequences set forth in Groups I-IV.

Applicants replied on July 21, 2005, electing Group IV (claims 16-52) with traverse. Applicants did not set forth grounds for the traversal. Claims 16, 20-24 and 27 were amended. Claims 33-52 were newly added.

The examiner mailed to applicants a Notice of an Incomplete Response on September 19, 2005, for failing to elect a species as required.

Applicants replied on October 19, 2005, electing SEQ ID NO: 18 (claims 31-33, 35, 37-45, 47 and 49-52) with traverse. Claims 16, 17, 33, 35, 37-40, 44, 45, 47 and 49 were amended. Claims 34, 36, 46 and 48 were canceled. Applicants argued that each of independent claims 16, 33 and 45 required the use of, or claims per se, "at least one peptide selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, and SEQ ID NO: 20" and thus were entitled to examination since, according to MPEP § 803.04, "normally ten sequences constitutes a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction."

The examiner mailed a supplemental restriction requirement to applicants on December 13, 2005, wherein two distinct inventions (Groups I-II) were identified and rationale set forth establishing the examiner's position. The claims were restricted as follows:

I. Claims 16-33, 35 and 37-44 drawn to methods of stimulating the immune system, classified in class 424, subclass 208.1.

II. Claims 45, 47 and 49-52, drawn to peptides, classified in class 530, subclass 350.

An election of species within the elected invention was also required as follows:

A. SEQ ID NO: 1
B. SEQ ID NO: 4
C. SEQ ID NO: 9
D. SEQ ID NO: 15.

Applicants replied on March 13, 2006, electing Group II, wherein the elected species was generic SEQ ID NO: 15 and ultimately SEQ ID NO: 18 (claims 45, 47 and 49-66), with traverse. Claims 53-66 were newly added. Applicants argued that the two groups were closely related and that a proper search of the claims of one groups would likely include a search of the claims of the other group as well. Applicants also continued to argue that each of independent claims 16, 33, 45 and 53 required the use of, or claims per se, "at least one peptide selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, and SEQ ID NO: 20" and thus were entitled to examination since, according to MPEP § 803.04, "normally ten sequences constitutes a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction."

The examiner mailed a new Office action on April 11, 2006, acknowledging the election of Group II, wherein the species is generic SEQ ID NO: 15 and specific sequence SEQ ID NO: 18, and the traversal. The examiner maintained the requirement and made it Final on the basis that the groups are directed to products and methods, and the products can be used in a materially different process. Claims 16-33, 35, 37-44 and 62-64 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicants' argument that normally up to ten nucleotide sequences are examined together was not found to be germane since the instant claims involve amino acid sequences. Claims 45, 47, 49-61 and 65-66 were

objected to. Claims 53-61, 65 and 66 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

Applicants filed a response to the Non-final Office action on October 5, 2006, along with this petition asking review of the restriction requirement.

DISCUSSION

The petition and case history has been considered carefully. The petition requests that the Office withdraw the restriction requirement between

(1) the product, claims 45, 47, 49-66 and the process of using the product, claims 16-33, 35, 37-44
(2) peptides of SEQ ID Nos 1, 4, 9 and 15
(3) peptides of SEQ ID Nos 16, 17, 18, 19 and 20.

(1) The restriction requirement between product and process

The examiner has restricted between product and process of using the product. In this case, the product is distinct from the process because it can be used for another materially different process, such as immunoassays or affinity purification. Applicant has elected the product for examination and none of the product claims are currently allowable. The following guidance informs applicants of potential opportunities for rejoinder, should all the elected product claims be found allowable.

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

(2) The requirement to elect a single peptide from SEQ ID NO 1, 4, 9 and 15.

It is noted that on December 13, 2005, the examiner mailed to applicants a supplemental restriction requirement wherein the claims were divided into two (2) groups as set forth supra. If applicants were to elect Group II, they were further required to elect one species selected from the group consisting of: SEQ ID NOs: 1, 4, 9 or 15. This requirement was improper. Independent claim 53, as currently pending, requires all of SEQ ID No 1, 4, 9 and requires one of the species encompassed by SEQ ID NO 15. Thus the peptides having SEQ ID No 1, 4, 9 and 15 (as a Markush group of species encompassed by SEQ ID No 15) are claimed together, as a set. The restriction requirement to a single peptide selected from the group consisting of SEQ ID No 1, 4, 9 or 15 may have been proper if the peptides had been claimed in the alternative. Because applicants are claiming peptides having SEQ ID NO 1, 4, 9 and 15 as a set, the requirement to elect one of the set is not proper as this requirement does not correspond to the invention as claimed. Applications claiming only a combination of polypeptide sequences, such as SEQ ID NO 1, 4, 9 and one species of SEQ ID No 15, as set forth in Claim 53, will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one polypeptide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual polypeptide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

(3) The requirement to elect a single peptide from SEQ ID NO 16, 17, 18, 19 and 20.

The product claims require a peptide selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19 and SEQ ID NO: 20. In contrast to the previous section, these peptides are recited in the alternative and not claimed as a set of required members.

As pointed out by applicants on page 3 of the instant petition, SEQ ID NOs: 16-20 are species of generic SEQ ID NO: 15 and read:

> SEQ ID NO: 16
> Lys Phe Ile Ile Pro Xaa Phe Ser Ala Leu Gly Gly Ala Ile Ser Tyr Asp Leu Asn Thr Xaa Leu Asn Cys Ile
>
> SEQ ID NO: 17
> Lys Phe Ile Ile Pro Xaa Phe Ser Ala Leu Ser Gly Gly Gly Ala Ile Ser Tyr Asp Leu Asn Thr Phe Leu Asn Cys Ile Gly
>
> SEQ ID NO: 18
> Arg Phe Ile Ile Pro Xaa Phe Thr Ala Leu Ser Gly Gly Arg Arg Ala Leu Leu Tyr Gly Ala Thr Pro Tyr Ala Ile Gly
>
> SEQ ID NO: 19

Lys Ile Ile Pro Xaa Phe Ser Ala Leu Gly Gly Gly Arg Leu Leu Tyr Gly Ala Thr Pro Tyr Ala Ile Gly

SEQ ID NO: 20
Arg Ile Ile Pro Xaa Phe Thr Ala Leu Ser Gly Gly Gly Arg Leu Leu Tyr Gly Ala Thr Pro Tyr Ala Ile Gly

In the absence of evidence to the contrary, the examiner reasoned that each isolated peptide selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19 and SEQ ID NO: 20 is a structurally distinct chemical compound. The generic peptide, SEQ ID NO 15 is not currently claimed.

The petition counters the Examiner's statement that each of the peptides having SEQ ID Nos 16-20 would have a distinct tertiary structure with the argument that all amino acid and nucleic acid sequences have tertiary structure. This is not persuasive for two reasons. First, an amino acid "sequence" is merely information, text on a page- it is the molecules comprising the sequence which have structure. Second, while applicants are correct that all amino acid and nucleic acid molecules have tertiary structure, the question which this decision needs to address is whether the tertiary structures are distinct from each other. In this instance, absent evidence to the contrary or an admission from applicants that the sequences are obvious one over another, the examiner is correct in asserting that the sequences are distinct from each other in view of their distinct tertiary structures.

Applicants also argue that the requirement for the election of one ultimate species of SEQ ID NO: 15 for examination is contrary to the spirit of MPEP § 803.04 which states that "normally ten sequences constitutes a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." This argument is not persuasive since this section of the MPEP is directed to "nucleotides" and not to polypeptides. Moreover, an OG Notice published March 27, 2007 rescinded the 1996 OG Notice that provided for a partial waiver of the requirements for restriction practice by permitting examination of a reasonable number, up to ten, independent and distinct polynucleotide molecules in a single 35 USC 111(a) or 35 USC 371 application. The Notice indicated that the standard of independence and distinctness would be applied to polynucleotide claims filed in an application under 35 USC 111(a).

Because the instant peptides having SEQ ID NO 16, 17, 18, 19 and 20 are distinct from each other and the examiner has shown that examination of the entire application would cause an serious burden, the instant restriction requirement to elect a single peptide from SEQ ID No 16, 17, 18, 19 and 20 is deemed proper. Currently, no pending claim recites SEQ ID No 15. SEQ ID No 15 encompasses all the species of SEQ ID NO 16, 17, 18, 19 and 20. Should a generic linking claim which recites SEQ ID No 15 and which encompasses all of the SEQ ID Nos 16, 17, 18, 19, and 20 be found allowable, applicant may be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided for by 37 CFR 1.141. See 821.04(a).

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above.

The restriction requirement between the product and process has been maintained.

The restriction requirement between peptides having SEQ ID Nos 1, 4, 9 and 15 has been withdrawn.

The requirement for an election of a single species of peptide from SEQ ID No 16, 17, 18, 19 or 20 has been maintained. Applicant has elected SEQ ID No 18 for examination.

The application will be forwarded to the examiner for consideration of the amendment filed October 5, 2006, and further action consistent with this decision, e.g., examination of SEQ ID No 18 and the combination of peptides having SEQ ID NO 1, 4, 9 and 18.

Should there be any questions about this decision, please contact Quality Assurance Specialist/Program Manager Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

John LeGuyader
Director, Technology Center 1600
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